# Overview of Good Publication Practice Guidelines GPP3



## Why All the Guidelines?

- Peer-reviewed publications have the power to impact medical practice, drive treatment decisions and patient outcomes and the guidelines help reinforce the standards of excellence
- Guidelines help direct the ethical, accurate, complete, and transparent reporting of medical research
- Lack of public trust in medical research and reporting of results



### Misconduct in Medical Research





Research Misconduct Identified by the US Food and Drug Administration

Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature

JAMA Internal Medicine April 2015 Volume 175, Number 4

## Behind the Veil: Conflicts of Interest and Fraud in Medical Research

on February 17, 2015 by Chris Kresser



Commentary:

Should you put your trust in medical research?

Cory Franklin June 8, 2015

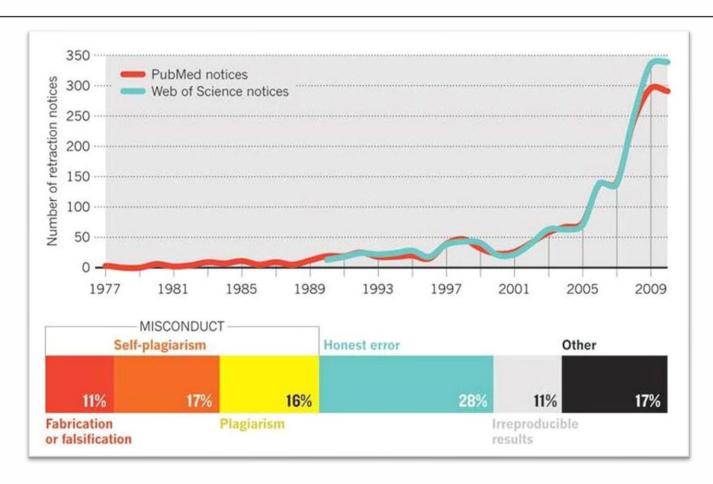
Mar 20, 2014 @ 11:53 AM 1,960 views



Medical Research Fraud And HHS's Office Of Research Integrity: Watching The Watchdog



### Retraction Notices are on the Rise

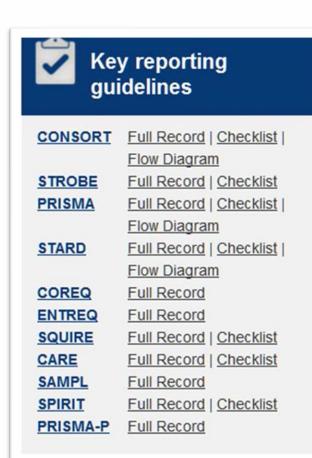




# Enhancing the Quality And Transparency Of Health Research



- http://www.equator-network.org/
- CONSORT randomized clinical trials
- STROBE observational studies in epidemiology
- PRISMA systematic reviews and meta- anlaysis (PRISMA- P – for related protocols)
- STARD diagnostic accuracy
- SPIRIT protocol standards
- CHEERS health economic reporting
- STRICTA acupuncture trials (extension of CONSORT)





# International Council Of Medical Journal Editors



Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals\*

About the Recommendations
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# Good Publication Practice Guidelines (GPP3)



The GPP3 guidelines were sponsored by the International Society for Medical **Publication Professionals** (ISMPP)



GPP3 guideline full Annals of Internal Medicine (AIM) article can be accessed through ww.ismpp.org/GPP3

## Why are GPP3 Guidelines Important?

- Provide guidance on how to responsibly and ethically develop and publish findings from clinical trials sponsored by pharmaceutical companies
- Demonstrate industry's commitment to integrity, accountability, and responsibility for accurate, complete and transparent reporting of companysponsored publications
- Broadly applicable to non-industry sponsored research such as academic and government funded work



# Why are GPP3 Guidelines Important? (Contd)

"If these efforts do not soon bring about a necessary sea change in the way industry funded trials are performed, the BMJ may well decide to stop publishing them. Whether an editor would survive such a decision is a question I may have to test."

Fiona Godlee, editor in chief BMJ 2014;348:g171



Battisti WP, et al. Ann Intern Med 2015. Smith R, et al. BMJ 2014;348:g171 doi: 10.1136/bmj.g171



### What's new in GPP3?

#### New elements include:

- 1. Guidance on updated ICMJE 2014 authorship criteria
- 2. Guidance on common issues regarding authorship
- Guidance and improved clarity on author payment and reimbursement
- 4. Additional clarity on what constitutes ghost or guest authorship
- ,5. Expanded information on the role and benefit of professional medical writers
- 6. Guidance for appropriate data sharing
- 7. Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues



# GPP3 Section 2.4: Professional Medical Writers

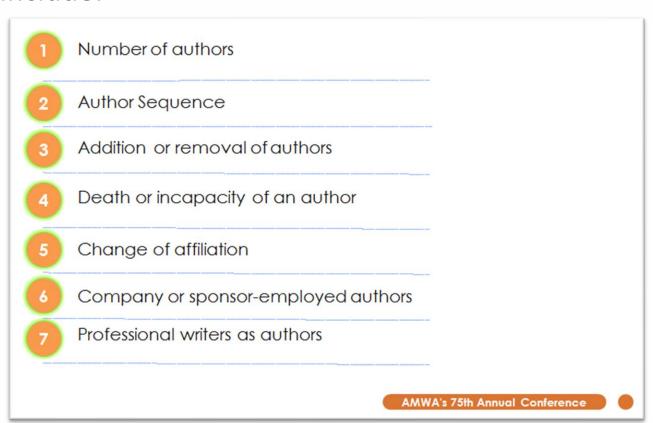
#### 2.4.2: Working With Authors

- The authors will control and direct the content of the publication or presentation. The writer must receive direction from the authors at the earliest possible stage (for example, before the outline is prepared)
- All authors have agreed to the writer's involvement.
- All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities.
- The authors will disclose, at a minimum, the writer's name, professional qualifications, affiliation, funding source, and any other information required by the journal or congress.
- Good publication practices will be followed.



## Common Authorship Issues

Most common authorship issues addressed in GPP3 include:





## **GPP3** Guidance on Authorship

#### GPP3 provides insights and examples to help clarify



- Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
- Drafting the work or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Authors must meet all 4 criteria

RESEARCH AND REPORTING METHODS

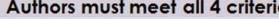
Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

Defines what is substantial contribution and what it is not with examples

Provides clarity on what constitutes a critical revision

Important for the author to read the entire manuscript

Each author is accountable for the work and should have confidence in the integrity of other authors' contributions



Academ



## Avoid guest- and ghost-writers

Authorship credit is based only on <u>substantial</u> contribution to:

- conception and design, <u>or</u> data analysis and interpretation
- drafting the article <u>or</u> revising it critically for important intellectual content
- and final approval of the version to be published

All these conditions must be met

Solely acquiring funding or collecting data does not justify authorship

All authors included on a paper must fulfil the criteria

No one who fulfils the criteria should be excluded

### Who did what?

Academ

Helen C Eborall, post-doctoral research fellow1, Simon J Griffin, programme leader2, A Toby Prevost, medical statistician1, Ann-Louise Kinmonth, professor of general practice1, David P French, reader in health behaviour interventions3, Stephen Sutton, professor of Behavioural science1

Contributors: SS, DPF, ATP, A-LK, and SJG conceived and designed the original protocol. All authors were involved in amending the protocol. HCE coordinated the study throughout. Data entry was carried out by Wyman Dillon Ltd, Lewis Moore, and HCE. HCE cleaned the data and ran preliminary analysis with input from Tom Fanshawe. ATP analysed the data. ADDITION trial data were supplied by Lincoln Sargeant and Kate Williams. HCE wrote the first draft of the manuscript with ATP and SS. All authors contributed to subsequent and final drafts. HCE is guarantor of the paper.

## Competing interests

A person has a competing interest when he or she has an attribute that is *invisible* to the reader or editor but which *may* affect his or her judgment

Always declare a competing interest, particularly one that would embarrass you if it came out afterwards



### Misconduct

 Fabrication: making up data or results and recording or reporting them

**Falsification:** manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record

**Plagiarism:** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit

### CrossCheck

web tool searches for overlapping content:

prepublication postpublication

specialist search engine (iThenticate)
uses "text fingerprinting" and "string matching"

gets behind access controls (unlike free tools) to search >9 billion articles in CrossRef database



## Good publication practice

- Read "Guidelines on good publication practice" from the Committee on Publication Ethics (COPE)
- Available free at www.publication ethics.org.uk



#### Table. What Is New in GPP3?

Guidance on updated ICMJE 2013 authorship criteria

Guidance on common issues about authorship

Guidance and improved clarity on author payment and reimbursement

Additional clarity on what constitutes ghost or guest authorship

Expanded information on the role and benefit of professional medical writers

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Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues

GPP3 = Good Publication Practice 3 guideline; ICMJE = International Committee of Medical Journal Editors.